

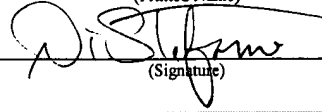


BEST AVAILABLE COPY

Atty. Dkt. No. 355908-2650

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David ELSLEY
Title: COMBINED THERAPIES FOR
ATHEROSCLEROSIS
TREATMENT
Appl. No.: 10/089,362
Filing Date: 1/14/2003
Examiner: Henley III, R.J.
Art Unit: 1614

CERTIFICATE OF EXPRESS MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service's "Express Mail Post Office To Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Mail Stop Issue Fee, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
EV 643 730 175 US (Express Mail Label Number)	23 March 2006 (Date of Deposit)
Laura DiStefano (Printed Name)	
 (Signature)	

APPLICATION FOR PATENT TERM ADJUSTMENT UNDER 37 C.F.R. § 1.705

Mail Stop Issue Fee
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicants hereby apply for patent term adjustment under the provisions of 37 C.F.R. § 1.705. This application is being filed along with payment of the Issue Fee and is accompanied by the fee as set forth in 37 C.F.R. § 1.18(e).

STATEMENT OF FACTS

The Notice of Allowance mailed 23 January 2006 indicates that the application is entitled to 185 days of Patent Term Adjustment.

03/28/2006 MBELETE2 00000066 10089362

01 FC:1463

200.00 DP

According to the Patent Term Adjustment History available on PAIR (hereinafter, the "PTA History"), Applicant has incurred 142 days in delays and the PTO has incurred 327 days in delays. Based on these delays, the application is entitled to 185 days of Patent Term Extension.

The PTA History indicates that the response to the non-final rejection mailed 4 February 2005 was received by the office on 23 September 2005. This date is incorrect.

The response to this non-final rejection was transmitted to the Office via Express Mail on 29 April 2005. The Office acknowledged receipt of the response by stamping the return postcard indicating a receipt date by OIPE of 29 April 2005. Copies of the Express Mail receipt and of the stamped return postcard are enclosed as Exhibit A.

In September 2005, attorneys for the Applicant were contacted by Examiner Henley, who indicated that the 29 April 2005 response had not been received by the Office. Applicant submitted a copy of the response including a copy of the Express Mail receipt and stamped return postcard to the Examiner via facsimile. Attached as Exhibit B is a copy of the response submitted by facsimile, as maintained in the image file wrapper at the PTO.

Therefore, rather than incurring 142 days of Applicant delay from 4 May 2005 (date of non-final office action plus 3 months) to 23 September 2005 (receipt of non-final office action response by the PTO), as currently shown in the PTA History, the Office incurred an additional 116 days of delay from 29 August 2005 (date of receipt of response to non-final office action by the PTO) to 23 December 2005 (mail date of Notice of Allowance).

For the Commissioner's convenience, a copy of data obtained from PAIR and data obtained from Applicants' Patent Term Calculation System, is provided, herewith as Exhibit C.

No Terminal Disclaimer has been filed.

CONCLUSION

In view of the above statements of fact, Applicants believe they are entitled to **443 days** of Patent Term Extension, based on 443 days PTO delay less 0 days Applicant delays.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872.

Respectfully submitted,

Date 23 March 2006

By Karen E. Flick

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1115
Facsimile: (650) 856-3710

Karen E. Flick
Attorney for Applicant
Registration No. 44,111



Mailing Label
Label 11-E, April 2004



UNITED STATES POSTAL SERVICE®

Post Office To Addressee

PRESS HARD. YOU ARE MAKING 3 COPIES.

ORIGIN (POSTAL SERVICE USE ONLY)		Customer Copy Label 11-F, April 2004	
PO ZIP Code	Day of Delivery	Postage	EXPRESS MAIL
94306	1	\$ 3.65	UNITED STATES POSTAL SERVICE®
Date Accepted	Scheduled Date of Delivery	Return Receipt Fee	Post Office To Addressee
4/23/04	4/23/04	\$ 0.00	
Time Accepted	Scheduled Time of Delivery	COD Fee	DELIVERY (POSTAL USE ONLY)
5:00 PM	11:00 AM	\$ 0.00	Delivery Attempt 1
Flat Rate	Int'l Alpha Country Code	Acceptance Emp. Initials	Time
1	000		AM
CUSTOMER USE ONLY		Employee Signature	
METHOD OF PAYMENT: CASH		Employee Signature	
Express Mail Corporate Acct. No.		Employee Signature	
650 856 3700		Employee Signature	
FROM: (PLEASE PRINT)		Employee Signature	
FOLEY & LARDER LLP		Employee Signature	
1530 PAGE MILL RD		Employee Signature	
PALO ALTO CA 94304-1125		Employee Signature	
555908-2650		Employee Signature	
LFS/mir		Employee Signature	
FOR PICKUP OR TRACKING: Visit www.usps.com or Call 1-800-222-1811		COMMISSIONER FOR PATENTS	
		PO BOX 1450	
		ALEXANDRIA VA 22313-1450	
		APR 29 2005	
		USPS 94306	

Title: COMBINED THERAPIES FOR ATHEROSCLEROSIS TREATMENT MAY 09 2005
Inventor(s): David ELSLEY Dkt. No. 355908-2650
Appl. No.: 10/089,362 GFS (4/29/05)

- Amendment (11 pgs.);
- Amendment Transmittal (3 pgs.).
- Executed Substitute Declaration (3 pages)

Due Date: April 29, 2005

Date Filed: May 4, 2005

Attorney Initials: GFS/mnr
Insp. By:

Insp. By:

Express Mail labeled EV 576653837 US



RECEIVED
CENTRAL FAX CENTER
SEP 23 2005

FOLEY & LARDNER LLP
ATTORNEYS AT LAW
1590 PAGE MILL ROAD
PALO ALTO, CA 94304-1125
TELEPHONE: 650.854.9700
FACSIMILE: 650.854.3710
WWW.FOLEY.COM

FACSIMILE TRANSMISSION

Total # of Pages 20 (including this page)

TO:	PHONE #:	FAX #:
Examiner Henley U.S. Patent and Trademark Office	571.272.0575	571.273.0575

From: Karen E. Flick
Email Address: kflick@foley.com
Sender's Direct Dial: 650.251.1115
Date: 23 September 2005
Client/Matter No: 355908-2650

MESSAGE:

Please see attaché.

If there are any problems with this transmission or if you have not received all of the pages, please call me at 1.650.251.1107.

Operator: Kitty YUEN	Time Sent:	Return Original To:
-------------------------	------------	---------------------

CONFIDENTIALITY NOTICE: THE INFORMATION CONTAINED IN THIS FACSIMILE MESSAGE IS INTENDED ONLY FOR THE PERSONAL AND CONFIDENTIAL USE OF THE DESIGNATED RECIPIENTS NAMED ABOVE. THIS MESSAGE MAY BE AN ATTORNEY-CLIENT COMMUNICATION, AND AS SUCH IS PRIVILEGED AND CONFIDENTIAL. IF THE READER OF THIS MESSAGE IS NOT THE INTENDED RECIPIENT OR ANY AGENT RESPONSIBLE FOR DELIVERING IT TO THE INTENDED RECIPIENT, YOU ARE HEREBY NOTIFIED THAT YOU HAVE RECEIVED THIS DOCUMENT IN ERROR, AND THAT ANY REVIEW, DISSEMINATION, DISTRIBUTION OR COPYING OF THIS MESSAGE IS STRICTLY PROHIBITED. IF YOU HAVE RECEIVED THIS COMMUNICATION IN ERROR, PLEASE NOTIFY US IMMEDIATELY BY TELEPHONE AND RETURN THE ORIGINAL MESSAGE TO US BY MAIL. THANK YOU.



EV 576633837 US



UNITED STATES POSTAL SERVICE®

Post Office To Addressee

ORIGIN (POSTAL SERVICE USE ONLY)				DELIVERY (POSTAL SERVICE USE ONLY)			
PO ZIP Code 91206	Day of Delivery Mon <input type="checkbox"/> Tue <input type="checkbox"/> Wed <input type="checkbox"/> Thu <input type="checkbox"/> Fri <input type="checkbox"/> Sat <input type="checkbox"/> Sun <input type="checkbox"/>	Postage \$ 13.65		Delivery Attempt	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature	
Date Accepted 04/29/05	Scheduled Date of Delivery Month: 5 Day: 2	Return Receipt Fee \$		Mo. Day	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature	
Mo. Day Year	Scheduled Time of Delivery Mon <input type="checkbox"/> Tue <input type="checkbox"/> Wed <input type="checkbox"/> Thu <input type="checkbox"/> Fri <input type="checkbox"/> Sat <input type="checkbox"/> Sun <input type="checkbox"/>	COO Fee \$	Insurance Fee \$	Mo. Day	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature	
Time Accepted 5:00 AM	Military <input type="checkbox"/>	Total Postage & Fees \$ 13.65		Delivery Date	Time <input type="checkbox"/> AM <input type="checkbox"/> PM	Employee Signature	
Flat Rate <input type="checkbox"/> or Weight 5 lbs.	Int'l Alpha Country Code	Acceptance Bmp. (Initials)		<input type="checkbox"/> WARRANTY OF SIGNATURE (Domestic Mail Only) Additional non-binding insurance is void if writer of signature is requested. I am delivery to be made without obtaining signature of addressee or addressee's agent or delivery employee (unless the office can be held secure by lockbox) and I authorize the delivery employee's signature (unless used for delivery). <input type="checkbox"/> NO DELIVERY <input type="checkbox"/> Weekend <input type="checkbox"/> Holiday			
CUSTOMER USE ONLY METHOD OF PAYMENT: <input type="checkbox"/> Bill Me <input type="checkbox"/> Credit Card <input type="checkbox"/> Debit Card <input type="checkbox"/> Money Order <input type="checkbox"/> Cash Express Mail Corporate Acct. No.				Return Agency Acct. No. or Postal Service Acct. No.			
FROM: (PLEASE PRINT) POLEY & LAROCK LLP 1000 PAGE MILL RD PALM ALTO CA 94304-1129 555908-2650				TO: (PLEASE PRINT) COMMISSIONER OF PATENTS PO BOX 145 ALEXANDRIA VA 22313-1450 APR 29 2005 APR 29 2005			
FOR PICKUP OR TRACKING: Visit www.usps.com or Call 1-800-222-1811							

Title: COMBINED THERAPIES FOR ATHEROSCLEROSIS TREATMENT MAY 09 2005²⁰
 Inventor(s): David ELSLEY Dkt. No. 335908-2650
 Appl. No. 10/089,362 GFS (4/29/05)

- Amendment (11 pgs.);
- Amendment Transmittal (3 pgs.);
- Executed Substitute Declaration (3 pages)

Due Date: April 28, 2005 Attorney Initials: GFS/mnr
 Date Filed: May 4, 2005 4/29/05 Insp. By:
 Express Hand Label EV 576633837 US





RECEIVED
CENTRAL FAX CENTER

SEP 23 2005

Atty. Dkt. No. 355908-2650

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David ELSLEY


Title: COMBINED THERAPIES FOR
ATHEROSCLEROSIS
TREATMENT

Appl. No.: 10/089,362

Filing Date: 1/14/2003

Examiner: Henley III, R.J.

Art Unit: 1614

CERTIFICATE OF EXPRESS MAILING	
I hereby certify that this correspondence is being deposited with the United States Postal Service's "Express Mail Post Office To Addressee" service under 37 C.F.R. § 1.10 on the date indicated below and is addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.	
EV 57663877	April 29, 2005
(Express Mail Label Number)	(Date of Deposit)
Rene C. Henley	
(Printed Name)	
	
(Signature)	

AMENDMENT TRANSMITTAL

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is an amendment in the above-identified application.

☒ Executed Substitute Declaration Enclosed.

☒ The fee required for additional claims is calculated below:

	Claims As Amended	Previously Paid For		Extra Claims Present		Rate		Additional Claims Fee
Total Claims:	22	- 28	=	0	x	\$50.00	=	\$0.00
Independent Claims:	4	- 4	=	0	x	\$200.00	=	\$0.00
First presentation of any Multiple Dependent Claims:					+	\$360.00	=	\$0.00
CLAIMS FEE TOTAL								= \$0.00

-1-

XXXX.XXXXXX.

- ☐ Applicant hereby petitions for an extension of time under 37 C.F.R. §1.136(a) for the total number of months checked below:

<input type="checkbox"/> Extension for response filed within the first month:	\$120.00	\$0.00
<input type="checkbox"/> Extension for response filed within the second month:	\$450.00	\$0.00
<input type="checkbox"/> Extension for response filed within the third month:	\$1,020.00	\$0.00
<input type="checkbox"/> Extension for response filed within the fourth month:	\$1,590.00	\$0.00
<input type="checkbox"/> Extension for response filed within the fifth month:	\$2,160.00	\$0.00
EXTENSION FEE TOTAL:		\$0.00
<input type="checkbox"/> Statutory Disclaimer Fee under 37 C.F.R. 1.20(d):	\$130.00	\$0.00
CLAIMS, EXTENSION AND DISCLAIMER FEE TOTAL:		\$0.00
<input checked="" type="checkbox"/> Small Entity Fees Apply (subtract ½ of above):		\$0.00
TOTAL FEE:		\$0.00

- ☐ Please charge Deposit Account No. 50-0872 in the amount of \$0.00. A duplicate copy of this transmittal is enclosed.
- ☐ A check in the amount of \$0.00 is enclosed.
- ☒ The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Respectfully submitted,

Date 4/29/05

By Gerald F. Swiss

FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1103
Facsimile: (650) 856-3710

Gerald F. Swiss
Attorney for Applicant
Registration No. 30,113

SEP 23 2005

Attorney Docket No. 355908-2650
Application Serial No. 10/089,362

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David ELSLEY
Title: COMBINED THERAPIES FOR
ATHEROSCLEROSIS
TREATMENT
Appl. No.: 10/089,362
Filing Date: January 14, 2003
Examiner: R. J. Henley III
Art Unit: 1614

CERTIFICATE OF MAILING
I hereby certify that this correspondence is being deposited with the
United States Postal Service with sufficient postage as Express Mail
in an envelope addressed to: Commissioner for Patents, P.O. Box
1450, Alexandria, VA 22313-1450, on the date below.

Rene Campos

(Printed Name)



(Signature)

EV 576633837

(Express Mail Label)

April 29, 2005

(Date of Deposit)

AMENDMENT AND REPLY UNDER 37 C.F.R. § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This Amendment and Reply is responsive to the non-final Office Action dated February 4, 2005, concerning the above-referenced patent application. This Office Action set a three month period for response and this Amendment and Reply is being filed on or before its due date of May 4, 2005.

Amendments to the Specification begin on page 2 of this document.

Amendments to the Claims are reflected in the listing of claims which begins on page 4 of this document.

Remarks/Arguments begin on page 8 of this document.

Please amend the application as follows:

Amendments to the Specification:

Please amend the specification as follows:

At page 5, lines 23-29, please amend the paragraph to read as follows:

A further aspect is a process for enhancing the reduction of serum lipid levels in a mammalian patient caused by administration of a cholesterol-lowering drug, which comprises administering to the patient an aliquot of the patient's own blood which has been treated ex-vivo ex vivo with one or more stressors selected from an oxidative environment, thermal stress and UV light and administering to the patient a cholesterol-lowering drug.

At page 11, line 29, to page 12, line 15, please amend the paragraph to read as follows:

A patient preferably undergoes a course of treatments of removal of a blood aliquot, treatment thereof as described above and re-administration of the treated blood to the patient, with the cholesterol-lowering drug being administered as separate doses during this course of treatments. Such a course may be a daily treatment for 4-6 days, followed by an interval and then a second course of daily treatments for 4-6 day. A preferred dosage regimen for the treated blood portion of the combination therapy is the administration of from 2-4 aliquots of autologous blood treated with stressors extracorporeally as described above, with the administration of any pair of consecutive aliquots being either on consecutive days, or being separated by a rest period of from 1-21 days on which no aliquots are administered to the patient, the rest period separating one selected pair of consecutive aliquots being from about 3-15 days. A more specific, preferred dosage regimen would be a total of three treatments and aliquots, with the first and second aliquots being administered on consecutive days and a rest period of 11 days being provided, between the administration of the second and third aliquots. The combination therapy of the invention may be useful in treatment of hypercholesterolemia resulting from all of the various aforementioned causes.

At page 15, lines 19-29, please amend the paragraph to read as follows:

One of the hallmarks of atherosclerosis is the presence of systemic endothelial dysfunction, an abnormality which can be demonstrated in both involved and non-involved distributive arteries, and at the level of the resistance arterioles in the microcirculation. Endothelial dysfunction is probably the earliest event in the atherosclerotic process and can be demonstrated in the presence of most risk factors for atherosclerosis, including hyperlipidemia, diabetes mellitus, hypertension and smoking, even before there is histological evidence of atherosclerosis. Thus studies which show significantly improved endothelial function in patients with atherosclerosis, for example, with the use of lipid lowering drugs and anti-oxidants, have been interpreted as indirect evidence of improvement of atherosclerosis.

Amendments to the Claims:

Please amend claims 21, 24, 25, and 31-44, as shown, below.

Please cancel claims 22, 23, and 45-48, without prejudice or disclaimer.

The following listing of claims will replace all prior versions and listings of claims in the application:

Listing of Claims:

Claims 1 to 20 (canceled):

Claim 21 (currently amended): In a method for treating atherosclerosis in a mammalian subject with a lipid profile modifying patient with a statin drug wherein the improvement comprises administering to the ~~mammalian subject~~ patient an aliquot of the ~~mammal's patient's~~ blood that has been treated ~~ex-vivo~~ ex vivo with one or more stressors, selected from the group consisting of oxidative stress, thermal stress, and UV light.

Claims 22 to 23 (canceled).

Claim 24 (currently amended): The method of claim ~~23~~ 21 wherein the statin drug is selected from the group consisting of atorvastatin, pravastatin, lovastatin, fluvastatin, simvastatin, and cerivastatin.

Claim 25 (currently amended): The method of claim 21 wherein the aliquot of the patient's blood has a volume of ~~about~~ from 0.1 to ~~about~~ 100 ml.

Claim 26 (currently amended): The method of claim 21 wherein the blood aliquot has been treated ~~ex-vivo~~ ex vivo with oxidative stress and UV light, and optionally with thermal stress.

Claim 27 (previously presented): The method of claim 26 wherein the oxidative stress is a chemical oxidizing agent, said chemical oxidizing agent being applied to the blood aliquot while the blood aliquot is subjected to UV light.

Claim 28 (previously presented): The method of claim 27 wherein the chemical oxidizing agent is a gaseous mixture of ozone and oxygen, said gaseous mixture being applied by bubbling through the blood aliquot while the blood aliquot is subjected to UV light.

Claim 29 (previously presented): The method of claim 28, wherein a thermal stressor, in the form of a temperature above or below normal body temperature, is applied to the blood aliquot simultaneously with the gas mixture and the UV light.

Claim 30 (previously presented): The method of claim 21 wherein the UV light stressor is UV light in the UV-C band wavelength.

Claim 31 (currently amended): The method of claim 21 wherein the stressors are applied *ex-vivo* ex vivo to the blood aliquot for a period of from about 2 to about 5 minutes.

Claim 32 (currently amended): The method of claim 24 wherein the ~~cholesterol~~ cholesterol ~~modifying statin~~ drug is atorvastatin administered at a daily dosage of from about 5 to about 200 mg.

Claim 33 (currently amended): The method of claim 24 wherein the ~~cholesterol~~ cholesterol ~~modifying statin~~ drug is pravastatin administered at a daily dosage of from about 5 to about 200 mg.

Claim 34 (currently amended): The method of claim 24 wherein the ~~cholesterol~~ cholesterol ~~modifying statin~~ drug is ~~simvastatin~~ simvastatin administered at a daily dosage of from about 5 to about 200 mg.

Claim 35 (currently amended): The method of claim 24 wherein the ~~cholesterol~~ cholesterol ~~modifying statin~~ drug is fluvastatin administered at a daily dosage of from about 5 to about 200 mg.

Claim 36 (currently amended): The method of claim 24 wherein the ~~cholesterol~~ cholesterol ~~modifying statin~~ drug is lovastatin administered at a daily dosage of from about 5 to about 200 mg.

Claim 37 (currently amended): The method of claim 24 wherein the ~~cholesterol~~ modifying statin drug is cerivastatin administered at a daily dosage of from about ~~5~~ 0.1 to about ~~200~~ 0.8 mg.

Claim 38 (currently amended): The method of claim 21 wherein administration of the ~~cholesterol-modifying statin~~ occurs prior to administration of the blood that has been treated ex vivo with one or more stressors.

Claim 39 (currently amended): The method of claim 21 wherein administration of the ~~cholesterol-modifying statin~~ drug occurs simultaneously with administration of the blood that has been treated ex vivo with one or more stressors.

Claim 40 (currently amended): The method of claim 21 wherein administration of the ~~cholesterol-modifying statin~~ drug overlaps administration of the blood that has been treated ex vivo with one or more stressors.

Claim 41 (currently amended): The method of claim 21 wherein administration of the blood that has been treated ex vivo with one or more stressors occurs prior to administration of the ~~cholesterol-modifying statin~~ drug.

Claim 42 (currently amended): A method of slowing or arresting the progression and/or effecting the regression of atherosclerotic plaque deposits and/or improving the stability of such plaques in a mammalian patient, the method comprising administering to the patient a ~~cholesterol-modifying statin~~ drug and an aliquot of the patient's own blood which has been treated ex vivo with one or more stressors, selected from the group consisting of an oxidative stress, thermal stress, and UV light.

Claim 43 (currently amended): A method of reducing serum lipid levels and/or combating the development of atherosclerosis in a mammalian patient, the method comprising:

a) administering to the patient an aliquot of the patient's own blood which has been treated ex vivo with one or more stressors, selected from the group consisting of, an oxidative stress, thermal stress, and UV light; and

b) administering to the patient a ~~cholesterol-lowering~~ statin drug.

Claim 44 (currently amended): A method of enhancing the reduction in serum lipid levels in a mammalian patient caused by administration of a ~~cholesterol-lowering~~ statin drug, the method comprising:

a) administering to the patient an aliquot of the patient's own blood which has been treated ex vivo with one or more stressors, selected from the group consisting of an oxidative stress, thermal stress, and UV light; and

b) administering to the patient a ~~cholesterol-lowering~~ statin drug.

Claims 45 through 48 (canceled).

REMARKS

Applicant respectfully requests reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Amendments to the Specification:

The specification was amended at page 5, line 29, to insert the inadvertently omitted word "drug" at the end of this paragraph. In addition, the underlined term "ex vivo" was replaced with the italics form to clarify that the previous underlining did not indicate added matter.

Typographical and grammatical errors were corrected at page 12, line 7 (removal of a space before the comma) and at line 10 (replacement of a comma with a period) as well as at page 15, line 22 (insertion of a period at the end of the sentence).

Amendments to the Claims:

Claims 21, 24, 25, and 31-44 are requested to be amended as shown, above.

Claim 21 has been amended to recite "[i]n a method for treating atherosclerosis in a mammalian patient with a statin drug . . ." The addition of the term "atherosclerosis" incorporates the Examiner's suggestion, as found at the top of page 6 of the Office Action as well as in previously presented Claim 22.

Similarly, the deletion of the phrase "lipid profile modifying" and addition of the term "statin" incorporates the Examiner's suggestion, as found in the middle of page 10 of the Office Action. Statins, as a class of lipid profile modifying drugs are disclosed throughout the specification, for example, in the paragraph bridging pages 2 and 3 and in previously presented Claim 23.

Support for the phrase "mammalian patient" can be found throughout the specification, e.g., at page 5, lines 21 and 25.

Finally, the term *ex vivo* has been changed in this and other claims to be in italics.

Claim 24 has been amended to depend from claim 21, since claim 23, from which claim 24 formerly depended, has been canceled.

Claims 25 and 31-37 have been amended to delete the term "about," as suggested by the Examiner at the bottom of page 6 of the Office Action.

Claim 31 has also been amended to delete the hyphen in the term "ex vivo," to conform to the other claims pending in the application and to place this term in italics.

Claims 32-44 have been amended to delete the phrases "cholesterol modifying" and "cholesterol lowering" and to add the term "statin," as suggested by the Examiner in the middle of page 10 of the Office Action.

Claim 37 have been amended to change the recited daily dosage range for cerivastatin from "about 5 to about 200 mg" to "0.1 to 0.8 mg," as suggested by the Examiner at the bottom of page 4 of the Office action. See, for example, page 15, lines 1-10, of the specification.

No new matter has been added by the above amendments.

Claims 22, 23, and 45-48, are requested to be canceled, without prejudice or disclaimer.

The above amendments have been made, in accordance with the Examiner's suggestions, to place the application in condition for allowance. Applicants are grateful to the Examiner for indicating allowable subject matter and suggesting claim amendments to overcome rejections. Nonetheless, Applicants reserve the right to file and prosecute continuation and/or divisional applications drawn to other aspects of the invention, including subject matter that has been canceled by the above amendments.

While the above amendments presumably obviate the outstanding objections and rejections, each will be separately addressed, below.

Oath/Declaration

Applicants submit herewith a new Oath/Declaration, which correctly identifies the application and related foreign filings.

Claim objections

Claims 23, 25, 32-41, and 45-47 were objected to for the recitation of "cholesterol modifying" and "cholesterol lowering." These phrases no longer appear in the claims.

Claims 25 was objected to for the recitation of "the patient," which allegedly lacked antecedent basis in claim 21. Claim 21 has been amended to provide antecedent basis.

Rejection under 35 U.S.C. § 112, first paragraph (written description)

Claim 37 was rejected because the specification allegedly lacked adequate written description for the recited daily dosage of cerivastatin. Claim 37 has been amended to conform to the daily dosage described in the specification.

Rejection under 35 U.S.C. § 112, first paragraph (enablement)

Claims 21-41 and 45-48 were rejected as allegedly not being supported by an enabling specification with respect to the full scope of the therapeutic objective. Claim 21, from which other claims identified in the rejection depend, has been amended to recite "atherosclerosis," as suggested by the Examiner, which presumably overcome the rejection. Note that claims 22, 23, and 45-48 have been canceled.

Rejection under 35 U.S.C. § 112, second paragraph (indefiniteness)

Claims 25 and 31-37 were rejected for the recitation of "about" with respect to certain ranges. While the term "about" appears to be standard claim language in U.S. patent applications and issued patents, it has nonetheless been deleted from the claims by the above amendments.

Rejection under 35 U.S.C. § 102(b)

Claims 21, 22, 38, 42-44, and 48 were rejected over Bisaccia *et al.* (U.S. Pat. No. 5,426,116) in view of the Merck Manual based on the Patent Office's interpretation of the phrases "lipid modifying drug" and "cholesterol-lowering drug." These phrases have been deleted from the claims as suggested by the Examiner at page 10 of the Office Action.

CONCLUSION

Applicant believes that the present application is now fully in condition for allowance.
Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is encouraged to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

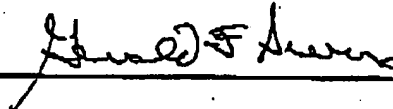
The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 50-0872. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 50-0872. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. § 1.136 and authorizes payment of any such extensions fees to Deposit Account No. 50-0872.

Respectfully submitted,

Date

4/29/08

By



FOLEY & LARDNER LLP
Customer Number: 38706
Telephone: (650) 251-1103
Facsimile: (650) 856-3710

Gerald F. Swiss
Attorney for Applicant
Registration No. 30,113

Atty. Dkt. No. 355908-2650

SUBSTITUTE DECLARATION

As a below named inventor, I HEREBY DECLARE:

My residence, post office address, and citizenship are as stated below next to my name;

I believe I am the original, first, and sole inventor (if only one inventor is named below) or an original, first, and joint inventor (if plural inventors are named below or in an attached Declaration) of the subject matter which is claimed and for which a patent is sought on the invention entitled

COMBINED THERAPIES FOR ATHEROSCLEROSIS TREATMENT**(Attorney Docket No. 355908-2650)**

the specification of which (check one)

☐ is attached hereto.☒ was filed on 1/14/2003 as United States Application Number or PCT International Application Number 10/089,362

I hereby declare that the subject matter of the (check one)

☐ attached amendment☒ amendment filed on 4/17/03

was part of my or our invention and was invented before the filing date of the above-identified original application for such invention.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment specifically referred to above.

I acknowledge the duty to disclose to the U.S. Patent and Trademark Office all information known to me to be material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56.

I hereby claim foreign priority benefits under Title 35, United States Code §119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or §365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate or of any PCT international application having a filing date before that of the application on which priority is claimed.

Page 1 of 3

XXXXXXX

Atty. Dkt. No. 355908-2650

Prior Foreign Application Number	Country	Foreign Filing Date	Priority Claimed?	Certified Copy Attached?
PCT/CA00/01112	PCT	09/25/2000	X	
2,283,374	Canada	09/24/1999		
2,283,975	Canada	09/28/1999		

I hereby claim the benefit under Title 35, United States Code § 119(e) of any United States provisional application(s) listed below.

U.S. Provisional Application Number	Filing Date

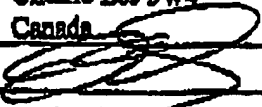
I hereby claim the benefit under Title 35, United States Code, §120 of any United States application(s), or § 365(c) of any PCT international application designating the United States of America, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT International application in the manner provided by the first paragraph of Title 35, United States Code, § 112, I acknowledge the duty to disclose information which is material to patentability as defined in Title 37, Code of Federal Regulations, § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

U.S. Parent Application Number	PCT Parent Application Number	Parent Filing Date	Parent Patent Number

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

XXXXXXXXXX

Atty. Dkt. No. 355908-2650

Name of first inventor	David ELSLEY
Residence	
Citizenship	Canada
Post Office Address	2320 Cheverie Street Oakville Ontario L6J 5W4 Canada
Inventor's signature	
Date	April 28, 2005

Page 2 of 3

XXXXXXXXXX



RECEIVED
CENTRAL FAX CENTER

SEP 23 2005

Atty. Dkt. No. 355908-2650

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: David ELSLEY

Title: COMBINED THERAPIES FOR
ATHEROSCLEROSIS
TREATMENT

Appl. No.: 10/089,362

Filing Date: 1/14/2003

Examiner: Henley III, R.J.

Art Unit: 1614

CERTIFICATE OF MAILING I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date below. <u>Rene Campos</u> (Printed Name) <u>[Signature]</u> (Signature) <u>May 13, 2005</u> (Date of Deposit)
--

CHANGE OF CORRESPONDENCE ADDRESS

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Applicant's attorney respectfully requests that the records of the United States Patent and Trademark Office in connection with the above-identified application be changed to show the following customer number for all future communications.

Customer Number: 38706

Respectfully submitted,

Date 5-13-05

By [Signature]

Gerald F. Swiss
Attorney for Applicant
Registration No. 30,113
Telephone: (650) 251-1103
Facsimile: (650) 856-3710

CLOSE WINDOW

ALL CASES SELECT CASE ACCOUNTS

Patent Term Adjustment Calculation System

Add a new event to this case

Docket Number: 355908-2650
Application Number: 10/089362
Patent Number: N/A

	Event Description	Event Date	Days from Filing	PTO Days	Applicant Days
Edit Delete	Application Filing Date	03/25/2002	-295		
Edit Delete	Notice to File Missing Parts	11/22/2002	-53		
Edit Delete	Response to Notice to File Missing Parts	01/14/2003	0		
Edit Delete	National Stage Entry (All 371 Requirements Met)	01/14/2003	0		
Edit Delete	IDS under 1.704(c)(8) filed at PTO	03/01/2004	412		
	14 month From Application date	03/14/2004	425		
Edit Delete	Non-Final Office Action	02/04/2005	752	327	
Edit Delete	Non-Final Office Action Response Received at PTO	04/29/2005	836		
	Non-Final Office Action Response Received at PTO + 4 months	08/29/2005	958		
Edit Delete	Notice of Allowance	12/23/2005	1,074	116	
	Projected Patent Grant Date	07/04/2006	1,267		
		Totals:		443	0
		PTA:		443	

Created and maintained by

FOLEY

VERSION: 3.01.00

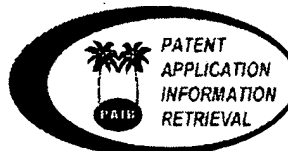
LOGIN: Loni Cummings

IP: 10.15.2.70

Foley & Lardner LLP



United States Patent and Trademark Office






[Home](#) | [Site Index](#) | [Search](#) | [FAQ](#) | [Glossary](#) | [Guides](#) | [Contacts](#) | [eBusiness](#) | [eBiz alerts](#) | [News](#) | [Help](#)
PATENT APPLICATION INFORMATION RETRIEVAL

Patent Term Adjustment (PTA) for publication number: 10/089,362			
			Days
Filing or 371(c) Date:	01-14-2003	USPTO Delay (PTO):	327
Issue Date of Patent:	-	Three Years:	-
Pre-Issue Petitions (days):	+0	Applicant Delay (APPL):	142
Post-Issue Petitions (days):	+0	Total PTA:	185
USPTO Adjustment (days):	+0	Explanation of Calculations	

Search Options

Assignments
Continuity Data
Display References
Foreign Priority
Image File Wrapper
File History
Publication Review

Patent Term Adjustment History			
Date	Contents Description	PTO (days)	APPL (days)
12-23-2005	Mail Notice of Allowance		
12-20-2005	Notice of Allowance Data Verification Completed		
12-20-2005	Case Docketed to Examiner in GAU		
09-23-2005	Oath or Declaration Filed (Including Supplemental)		
10-13-2005	Date Forwarded to Examiner		
09-23-2005	Response after Non-Final Action		142
03-30-2005	Correspondence Address Change		↑
01-27-2005	Information Disclosure Statement (IDS) Filed		↑
02-04-2005	Mail Non-Final Rejection	327	↑
02-03-2005	Non-Final Rejection	↑	
01-21-2005	IFW TSS Processing by Tech Center Complete	↑	
01-21-2005	Case Docketed to Examiner in GAU	↑	
03-01-2004	Information Disclosure Statement (IDS) Filed	↑	
01-14-2003	371 Completion Date	↑	
06-15-2004	Application Dispatched from OIPE	↑	
06-15-2004	Notice of DO/EO Acceptance Mailed	↑	
01-14-2003	Additional Application Filing Fees	↑	
04-17-2003	Preliminary Amendments	↑	
01-14-2003	A statement by one or more inventors satisfying the requirement under 35 USC 115, Oath of the Applic	↑	

03-05-2004	Withdraw Pre-Exam Abandon		
05-27-2004	Petition to Revive Application - Granted		
01-14-2003	Petition Entered		
04-30-2004	Cleared by OIPE CSR		
03-04-2004	Abandonment -- Inc. Application under Rule 53(b) - Filing Fee Paid		

**This Page is Inserted by IFW Indexing and Scanning
Operations and is not part of the Official Record**

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images include but are not limited to the items checked:

- ☐ BLACK BORDERS
- ☐ IMAGE CUT OFF AT TOP, BOTTOM OR SIDES
- ☐ FADED TEXT OR DRAWING
- ☐ BLURRED OR ILLEGIBLE TEXT OR DRAWING
- ☐ SKEWED/SLANTED IMAGES
- ☐ COLOR OR BLACK AND WHITE PHOTOGRAPHS
- ☐ GRAY SCALE DOCUMENTS
- ☒ LINES OR MARKS ON ORIGINAL DOCUMENT
- ☐ REFERENCE(S) OR EXHIBIT(S) SUBMITTED ARE POOR QUALITY
- ☐ OTHER: _____

IMAGES ARE BEST AVAILABLE COPY.

As rescanning these documents will not correct the image problems checked, please do not report these problems to the IFW Image Problem Mailbox.